

REMARKS

In the Office Action, the Office rejects pending claims 54-59 and 61-76.

Applicants submit the following remarks for the Office's consideration.

In addition, Applicants have amended the specification to promote consistency within the specification. Specifically, Applicants amend the definition of "fermenting" and "fermentation" in paragraphs, [0009], [0029], and [0040], of the published application to include "aerobic" fermentation, to be consistent with examples 2, 3, 4, and 6 in the specification. For example, Example 2 describes that for "bacterial growth condition, the agitation and **aeration** rate were set at 450 rpm and 3vvm, respectively", and during fermentation, "the conditions remained unchanged except agitation was adjusted to 350 rpm." See paragraphs [0075] and [0076] (emphasis added). Thus, the amendment adds no new matter.

I. Prior Rejections / Objections

Applicants note with appreciation that the Office has withdrawn the objection to claim 61 in light of Applicants' amendments to the claim. Office Action at page 2.

Applicants also note with appreciation that the Office has withdrawn the rejections of claims 54 and 60 under 35 U.S.C. §112, second paragraph, as well as the rejections under the first paragraph of Section 112 presented in Sections 8-10 of the previous Office Action in view of the amendments and arguments previously presented. Office Action at page 2.

II. New Rejections

Rejection of Claims Under 35 U.S.C. 112, 1st paragraph

The Office rejects claims 54-59 and 61-74*. The Office rejects these claims under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. Specifically, the Office asserts that “the claims are drawn to an unlimited number of microorganisms used in the fermentation step ... a skilled artisan would be required to determine which exact species of microorganism works at all in the claimed invention”. Office Action at page 3. Applicants respectfully traverse.

As is well established, a specification may meet the enablement requirement where experimentation may be required to practice the invention so long as the experimentation is not undue. MPEP 2164.01 at 2100-193 (rev. 3, August 2005). Indeed, even if experimentation is complex, it may not be “undue” if it is routine. *Id.*

The practice of this invention is far from complex, and any experimentation is entirely routine. The invention relates to microorganisms that ferment collagen-containing tissues to permit production of a collagen composition weighing at least about 10% of the weight of the collagen-containing tissues and comprising mostly collagen monomers. Any experimentation required to select the microorganism for carrying out the invention involves basic skills in microbiology.

The process of fermentation involves the growth of microbes, and any microbiologist who has studied just college level microbiology would know how to grow

* Applicants believe the Office intended this rejection to apply to all pending claims 54-59 and 61-76 and have responded accordingly. If this is incorrect, Applicants respectfully request clarification.

microbes. Indeed, the conditions suitable for the growth of different kinds of bacteria, i.e., the appropriate media and pH, can be easily found in the Bergey's Manual. For other microbes, such a person would know to consult various bio-resource centers, such as ATCC (American Type Culture Collection) or DSMZ (German Collection of Microorganisms and Cell Cultures). Thus, the determination of the appropriate conditions for growing microbes for fermentation is very straight forward, totally routine, and not at all complex.

In addition, those of skill in any biological field would know how to assess the amount of collagen in tissues after fermentation. For example, to determine if the yield of collagen is at least about 10% of the weight of collagen-containing tissues, one would weigh the collagen material both before and after the fermentation as described in paragraph [0082] of the instant application. See also column 7 of lines 56 - 64 of U.S. Patent No. 5,436,135, also noted in [0082]. Finally, to determine the presence of collagen monomers, weighing about 95-100 kDa, the skilled person would use the well-known and totally conventional method of SDS -polyacrylamide gel electrophoresis as shown in the working examples in the specification.

The routine screening of microbes using these steps does not take a long time. Indeed, the inventors have informed the undersigned that the entire process, from the growing of microorganism, fermentation of collagen-containing tissues, enzyme/acid treatment, precipitation of collagen, to the analysis of amount and type (presence of monomers) of collagen produced, takes about 7-8 days. Moreover, the routine screening can be carried out in parallel in hundreds of experiments. Thus, the amount

of effort involved is not at all excessive or undue, and species with a high yield of collagen monomers can be readily and quickly selected through the routine screening.

As compared to *Wands*, there can be no question that any experimentation here is not undue. In *Wands*, one experiment involved immunizing the animal, waiting for immune response to obtain the lymphocytes, fusing lymphocytes with myeloma cells, cloning the hybridoma, and screening the antibodies for the desired characteristics, and it took at least over two months, given the time-consuming immunization protocol for monoclonal antibody production.

Finally, as regards the *Wands* factors, Applicants note the considerable direction and guidance in the disclosure. The disclosure provides six detailed actual working examples with bacillus and yeast, involving different types of animal tissues. Thus, the nature of the invention and state of the prior art on fermentation and collagen assays, coupled with the level of skill in the art and the amount of direction provided by the specification, all demonstrate that this invention can be fully practiced with routine skill.

In view of the foregoing remarks, Applicants submit that the specification fully enables the claims. Withdrawal of the rejection of claims 54-59 and 61-76 is respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims. And, in light of the three office actions issued in this case, Applicants earnestly request that the Office contact their representative to set up an interview if the Office does not consider the application to be allowable.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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